

**Meeting with the Medi-Cal Pharmaceutical Contracting Section
Frequently Asked Questions (FAQ)
About Medical Supplies/Enteral Formulas Contracting**

You have been invited to meet with the Department regarding your *petition* to add an individual medical supply/enteral formula to our List of Contract Medical Supply/Enteral Formula (List), or as part of a Product Category Review (PCR) to place, or continue the presence of, one or more medical supplies/enteral formulas on the List. The general process for placement of a product on the List includes a proposed contractor presentation, a proposed contractor business proposal, and a State/proposed contractor *contract negotiation* process. This is not a *formal invitation to bid* contracting process. Many proposed contractors have no idea what to expect or how to prepare when they schedule an appointment to present a medical supply/enteral formula to us, or what goes on in the actual presentation. This document contains some frequently asked questions that will help you prepare for your meeting with the Department. Much more detailed information is available in the Medi-Cal Medical Supplies/Enteral Formulas Review Procedures document.

Q1: How long is the meeting?

Typically we schedule the meeting room for one and one-half hours. This leaves time for a one-hour presentation, plus questions. There generally will not be an opportunity for a second meeting, so budget your time carefully.

Q2: Do you provide audio-visual equipment?

No, we have no audio-visual equipment available. Our meeting rooms have electrical outlets only. You must provide your own projectors, laptops, extension cords, etc.

Q3: Who will attend from the Department?

Typically the project manager who has been assigned to your medical supply/enteral formula will attend, sometimes with other staff. Occasionally staff from other DHS programs may attend. If you have handouts for your presentation and have not sent them in ahead of the presentation, please bring enough copies for the Department staff attending.

Q4: Whom should we bring to the meeting?

That is up to you. We typically meet in various conference rooms in our building, as necessitated by scheduling. Most of our meeting rooms will hold six to ten people. The Department usually assigns one or two persons to attend, leaving four to eight persons that the proposed contractor can bring. It has been our experience that bringing more people than this does little to enhance the presentation. Please be sure to tell the project manager assigned your medical supply/enteral formula the names of individuals you plan to bring, in advance, so that we can schedule an appropriately sized room, and notify our security desk of your arrival.

Some proposed contractors send the medical supply/enteral formula's product manager, attorneys, local, regional and national sales managers, and financial experts. Others send only one or two people as spokespersons. You should bring one or two medical experts on the product who can discuss the product from a prescriber's medical use perspective. If applicable, it might also be desirable to bring your contract manager. Be prepared to name and provide contact information for the legal contracting authorities for your company.

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Q5: What should we talk about?

The Department will evaluate your medical supply/enteral formula using our five criteria – Safety, Efficacy, Essential Need, Misuse Potential, and Cost. The individuals attending the meeting should address these criteria, e.g., what makes this medical supply/enteral formula safer or more effective than other medical supplies/enteral formulas the Department has, or is considering for its List? Why does the Department need this medical supply/enteral formula, if other similar medical supplies/enteral formulas are already on the List? What are the chances that prescribers will misuse this medical supply/enteral formula (i.e., prescribe this medical supply/enteral formula when equally efficacious but less expensive medical supplies/enteral formulas are available or appropriate)? What makes this medical supply/enteral formula cost-effective to the Department? We discuss the Cost criterion in more detail later in this document.

With regard to the Cost criterion, you should make a business proposal that addresses the cost of the item to the Department. In some cases, that will involve an offer of a rebate paid to the State (such as in a Rebate Contract), or a Maximum Acquisition Cost (MAC), or a Net Cost Contract, or a combination of a MAC and a Net Cost Contract.

Q6: What is a Rebate, a Maximum Acquisition Cost, a Net Cost, and a combination agreement?

Some product categories are restricted to one agreement type. Other product categories may propose more than one type of approach to an agreement. Before assembling a cost proposal, speak with your project manager in the Department to identify if your product category is restricted.

- *A rebate agreement offers a percent of the pricing index currently used by the Department to reimburse providers..*
- *A Maximum Acquisition Cost agreement guarantees an acquisition cost as the maximum selling price to all providers.*
- *A Net Cost agreement guarantees a fixed net cost to the Department.*
- *A combination agreement guarantees both a MAC to all providers and a net cost to the Department.*

Q7: What should we bring to our meeting?

Be prepared to address the Five Criteria and bring a written business proposal that includes all cost information for the type of agreement you choose, or that is required.

When requested, bring samples of the exact products in your business proposal.

Bring information on your current and planned marketing efforts for this product, including direct-to-consumer marketing materials. Bring examples of your direct-to-consumer marketing materials and information about any co-op advertising agreements. Provide us with your product marketing plan.

If applicable, bring your company's history regarding payment of product rebates to the Department. For example, what is the total of your company's rebates for the past year? How much has your company paid us? How much has your company disputed and why? What steps has your company taken to resolve any disputes?

Q8: We don't like disputes either. How can we avoid them?

Some products, by their very nature, tend to generate more disputes than others. Many disputes cannot be avoided, and proposed contractors will reduce their workload if they know how the products are used and how the products should be billed (by the box, each, can, case, milliliter, gram, etc.). Keep things simple.

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Q9: What information do you need in our business proposal?

For each product in question, please provide us with the exact name of the item, Universal Product Number, catalog item number, HCPCS Number, size (if applicable), and your cost proposal (Rebate, Maximum Acquisition Cost, Net Cost agreement, or combination).

Q10: What happens after our meeting?

*The project manager assigned to the product category will present the medical supply/enteral formula to other staff in the Department, addressing the five criteria. If the Department has additional questions, the project manager will contact you for more information. A decision will then be made. The choices typically are to add the medical supply/enteral formula as proposed, to reject the petition, or to make a counter-proposal. **Reminder: this is a contract negotiation process that can result in several proposed contractors products appearing on the "List". This is not a competitive bid process that will result in a sole source proposed contractor product on the list.***

Counter-proposals usually involve a change in the proposed price and/or rebate, and sometimes a "Code 1" restriction of some type, such as limiting the medical supply/enteral formula's use to patients with a certain diagnosis, a certain age, weight status, etc. The counter-proposal is usually made over the telephone. We generally give the proposed contractor a specified length of time to respond to our counter-proposals.

Project managers will develop an ongoing review process schedule. You may call the project manager assigned to your medical supply/enteral formula periodically to check on the status of your product review.

Q11: How does the Department evaluate cost?

Evaluation will be based on the cost of the product plus provider reimbursement, minus any applicable rebate.

Q12: What aspects of the contract negotiation process are confidential?

Confidentiality requirements are applicable to the Product Category Review AND the Petition processes described in this document. Confidentiality is required of all participants engaged in the contracting process. All anti-trust and collusion laws must be strictly adhered to by all. This includes, but is not limited to:

- **active promotion** of products proposed for addition to the List shall not occur until the provider bulletin is published; AND
- prices proposed to the Department, counter offers from the Department, and final contracted prices shall not be **shared or announced** until the provider bulletin is published; AND
- Failure to comply with confidentiality requirements may result in a delay of the addition of products to the List, or cancellation of the contract.

Q13: How do I know which medical supplies/enteral formulas are already on the List ? Where can I learn about the other aspects of the Pharmacy Program?

The List is published in our Pharmacy Provider and Allied Health Provider Manuals. The easiest way to see the List is to go to the Department's web site, www.medi-cal.ca.gov. Click on Provider Manual, "Pharmacy", and on the next page click on "Part 2-Pharmacy" for both medical supplies and enteral

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formula information. Other Program Manuals are also available on this site. The Provider Manuals are the most comprehensive reference on the Medi-Cal pharmacy program, and contain answers to many questions.

Q13: Can I get a copy of the contract we will need to sign with the Department?

Ask the project manager in charge of your medical supply/enteral formula's review for a copy of our boilerplate contracts. It is important to have your company review our boilerplate contract language ahead of time so that if your product is added to the List, the boilerplate contract can be signed quickly.

Q14: How can I get data on the Department utilization of our product, and of our competitor's products?

Please contact the project manager assigned to your review.

- *For products with National Drug Codes (NDCs) paid through the drug program you can download monthly and quarterly reports of fee-for-service pharmacy utilization, in NDC order on our web site, free of charge. Go to www.dhs.ca.gov/mcs/mcpd/MBB/contracting/files*
- *The Department publishes monthly, quarterly, and annual reports of fee-for-service pharmacy utilization, in NDC order. These are available for public viewing at the California State Library Government Publications Section, which is currently located at:
914 Capitol Mall, Fourth Floor
Sacramento, CA 95814
Phone: 916-654-0069*
- *The Department's Medical Care Statistics Section can assist you in obtaining more detailed data, and in its analysis, for a fee. On the Internet, go to www.dhs.ca.gov/mcss for more information. If you can't find what you need on the website contact [contact](mailto:jwatkins@dhs.ca.gov) Jim Watkins, Chief of the Medical Care Statistics Section at jwatkins@dhs.ca.gov*

Q15: I have more questions. Where can I get answers?

Call the project manager assigned to review your medical supply/enteral formula. He or she can answer your questions.

Again, we encourage you to carefully read our Medi-Cal Medical Supplies/Enteral Formulas Review Procedures document, which explains many of these points in much greater detail than given here. If you don't have a copy of that document, please request a copy from your assigned project manager.